Microwave Endometrial Ablation vs. Rollerball Electroablation for Menorrhagia: A Multicenter Randomized Trial

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Study Objective. To compare the effectiveness, safety, and acceptability of microwave endometrial ablation (MEA) with those of rollerball electroablation (REA) for the treatment of menorrhagia.

Design. Randomized clinical trial (Canadian Task Force classification I).

Setting. Eight academic medical centers and private medical practices.

Patients. Three hundred twenty-two women with documented menorrhagia due to benign causes.

Intervention. MEA or REA.

Measurements and Main Results. By intent-to-treat analysis, the success rate of MEA at 12 months (87.0%; CI 81.7%–91.2%) did not differ significantly (p = .40) from that of REA (83.2%; CI 74.7%–91.2%). Among evaluable patients, success rate was also similar (p = .24) in the MEA (96.4%; CI 92.7%–98.5%) and REA (92.7%; CI 85.6%–97%) groups. The amenorrhea rate in evaluable patients after MEA was 61.3% (CI 54.1%–68.2%). In patients with myomas, the success and amenorrhea rates in evaluable patients after MEA were 90.3% (CI 74.2%–98%) and 61.3% (CI 42.2%–78.2%), respectively. In evaluable patients with body mass index of 30 kg/m² or greater, MEA success rate was 96.7% (CI 88.5%–99.6%) compared with 81.8% (CI 59.7%–94.8%) for REA (p = .042). The ablation procedure was performed under IV sedation in 62% of patients in the MEA group versus 18% of patients in the REA group (p < .001); whereas, general anesthesia was employed more often in patients undergoing REA (37% vs. 76%, p < .001). No major complications were encountered. Patient satisfaction with results of treatment was high (98.5% of the MEA and 99.0% of the REA group).

Conclusions. Microwave endometrial ablation is an efficacious and safe procedure for the treatment of menorrhagia. Over half of patients treated with MEA achieve amenorrhea, and the procedure is suitable for women with myomas and irregular uterine cavities. The procedure is easily learned and can be performed rapidly, under IV sedation in most cases.

Microwave endometrial ablation (MEA) is a nonhysteroscopic thermal technique that is easily learned, can be performed usually in less than 5 minutes, and does not require irrigation fluid with the attendant risk of fluid overload. It was first used to treat menorrhagia in 1996. In the past decade, approximately 25 000 MEA procedures have been performed. In a previous randomized controlled trial (RCT) comparing MEA with TCRE, patients treated with MEA reported high rates of satisfaction and acceptability and an improved quality of life. In that RCT, 79% of women undergoing MEA were completely or generally satisfied with therapeutic results after microwave ablation compared with 67% treated by TCRE 2 years after treatment.

Endometrial ablation has proven to be a safe, effective, and less-invasive alternative to hysterectomy in the management of menorrhagia due to benign causes. The first-generation endometrial ablation techniques such as rollerball electroablation (REA) and transcervical resection of the endometrium (TCRE) are employed in operative hysteroscopic procedures that require a lengthy learning period and considerable surgical skill and technical proficiency to achieve optimal clinical outcomes. A number of second-generation thermal endometrial ablation techniques, which do not require operative hysteroscopy skills and provide effectiveness equal to that of REA and TCRE, have been developed to reduce the technical demands made upon the surgeon.

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In this report, results are presented from a phase III prospective, multicenter, randomized trial comparing MEA with REA with respect to reduction in clinical menorrhagia at 12 months posttreatment. Patient satisfaction, quality of life, and procedure safety are also described.

Materials and Methods

Study Design
This prospective, multicenter, randomized comparison of MEA and REA was conducted between April 2000 and September 2001 by the Microwave Endometrial Ablation Group (Appendix) of 16 investigators at five sites in the USA, two in Canada, and one in the UK. The study was approved by the institutional review boards of the participating sites. All patients were counseled, and written informed consent was granted.

The study was designed to assess the equivalence of MEA and REA in treating menorrhagia. The primary study endpoint was menstrual blood loss per cycle as documented by the pictorial blood loss assessment chart (PBAC) originally designed by Higham et al.5 and validated and refined by Janssen et al.6 As recommended by the US Food and Drug Administration, the criterion of treatment success adopted was a postprocedure PBAC monthly diary score of 75 or less. Secondary endpoints included amenorrhea rate, duration of procedure and anesthesia, type of anesthesia, device-related complications, adverse incidents, dysmenorrhea, quality of life assessed by SF-36 Health Survey questionnaire score (SF-36),7 and patient satisfaction and acceptability of treatment.

Patients
Eligible study participants were nonpregnant premenopausal women older than 30 years of age with no plans to become pregnant in the future. Candidates must have failed or refused medical therapy or have proved unable to tolerate such therapy. A PBAC score of 185 or higher (documented for 1 month or, in the absence of earlier documented menorrhagia, average PBAC score over 3-month period) was required. At enrollment, follicle-stimulating hormone levels were required to be 30 IU/mL or less and the uterine cavity sounding length to be from 6 to 14 cm. Before randomization, women underwent a transvaginal ultrasound examination in the transverse and sagittal views to determine that the myometrial wall thickness was 8 mm or more in its thinnest area and to identify existing uterine pathology. Enrollment of women with submucosal myomata 3 cm or less that did not obstruct access to the uterine cavity was allowed. An endometrial biopsy or dilatation and curettage was required within 6 months of enrollment to confirm that no endometrial hyperplasia or carcinoma was present. A documented normal Pap smear within the previous 6 months was also required. Women with a myometrial wall thickness of less than 8 mm, active endometritis, endometrial hyperplasia, endometrial carcinoma, active pelvic inflammatory disease, previous endometrial ablative surgery, previous classic cesarean section, a history of gynecological malignancy within the past 5 years, untreated or un evaluated cervical dysplasia, and known clotting defects or bleeding disorders were excluded. Women with an intrauterine device were excluded from participation.

Treatment group assignments were made using computer-generated random numbers in a 2:1 ratio of MEA to REA treatment by site. This randomization ratio was selected to increase the precision with which the effects of the novel therapy (i.e., MEA) could be assessed. Since some evidence indicates that increasing age is associated with higher rates of amenorrhea and complete relief of dysmenorrhea after endometrial resection, stratification was used to ensure proportionate representation of patients less than 40-years old and patients 40-years old or older in the two study groups. After being randomized, patients were given a single hormonal pretreatment of leuprolide acetate depot 3.75 mg IM to thin the endometrial lining 3 to 5 weeks before the endometrial ablation procedure. Timing of leuprolide administration in relation to the menstrual cycle was at the discretion of the investigator.

Treatment
Surgeon, anesthesiologist, and patient preferences determined whether MEA and REA were performed under local, regional, or general anesthesia, as well as the use of concomitant IV sedation in conjunction with local anesthesia. Perioperative antibiotic and nonsteroidal anti-inflammatory drug suppository use were at the discretion of the surgeon. Cervical dilation to 9 mm followed by CO2 hysteroscopy was performed to exclude an inadvertent false passage or perforation. A microwave applicator of 8.5 mm diameter (Microsulis Medical Ltd., Denmead, Hampshire, UK) was gently inserted until the distal tip reached the uterine fundus (Figure 1). The MEA device, which coagulates the endometrial tissue, is a radiating energy source utilizing microwaves at 9.2 GHz that emanate hemispherically from the applicator tip. The microwaves penetrate to 3 mm resulting in thermal destruction of the surrounding uterine tissue to 5–6 mm. The applicator does not require direct endometrial contact. The applicator is a reusable device that contains a microchip to record a history of usage and is returned to the manufacturer at the end of its usable life of 30 treatments. A thermocouple residing at the tip of the applicator provides continuous tissue temperature measurements, which are displayed in real-time on the user interface screen of the MEA console to allow continuous monitoring during therapy (Figure 2). This temperature profile is also saved in the MEA console for future reference, if needed.

Once the previously determined uterine sounding length was confirmed by demarcations on the applicator probe, the procedure began with a gentle side-to-side sweeping movement of the fundal area as the temperature rose to the desired treatment range of 70–80°C. Once the temperature of 70°C was reached, the applicator was briefly (approximately 5 seconds) displaced laterally to the two cornual areas. Finally the corpus of the uterus was treated with a continuous sweeping motion as the applicator was being withdrawn in 0.5-cm increments.
Women randomized to REA had the procedure performed according to the standard technique employed by the study surgeon. Women with myomas receiving REA treatment underwent a wire loop resection of the myoma followed by the rollerball procedure. All investigators were experienced in the performance of REA. Each investigator received thorough training in the use of MEA before treatment of the study patients. Initial MEA procedures were proctored by an experienced MEA preceptor.

**Follow-Up**

Postprocedure PBAC diaries were maintained for 12 months by all study participants. Additional postprocedure data collection, including patient questionnaires, adverse events, and quality of life evaluations, were completed at day 1, day 14, and 3, 6, and 12 months. SF-36 questionnaires were completed before treatment and at 3.6, and 12 months posttreatment and scored by an independent consulting group (Quality Metrics, Lincoln, RI). The study protocol mandates that patients will also complete case report forms and SF-36 questionnaires at 2 and 3 years postprocedure.

**Statistical Analysis**

Study data were analyzed both for the intent-to-treat (ITT) and evaluable patient populations using SPSS statistical software (SPSS, Inc., Chicago, IL) and StatXact 5.0.3 (Cytel Software Corp., Cambridge, MA). In the ITT analysis, patients lost to follow-up and those with missing data were counted as failures; whereas, such patients were excluded for purposes of evaluable patient analysis. The primary efficacy analysis performed on the ITT and evaluable populations employed Z statistics obtained from the normal approximation of the binomial distribution using an acceptable clinical difference, or delta, of 15% in the ITT population. Planned sample size was predicated on an equivalence hypothesis and calculated by the Blackwelder method\(^9\) to achieve a power of 80% at the one-sided 0.05 \(\alpha\) level based on a reduction of the monthly PBAC score to 75 or less in approximately 84.3% of patients treated by REA at 1-year follow-up. Center-to-center differences in success rate were evaluated by exact test for homogeneity of odds ratios. Fisher exact test was used with nominal data for comparisons between the MEA and REA groups. Differences in continuous data were assessed by \(t\) test. Between-group difference in apportionment of patients across ordered PBAC outcome categories was evaluated by exact Kruskal-Wallis test. Point estimates of success and amenorrhea rates are presented with exact 95% CI.

**Patient Disposition**

A total of 322 women participated in the study, of whom 215 were randomized to MEA and 107 to REA (Figure 3). Six patients did not undergo MEA because it was determined on the operative day that they had either limited
cavity access due to submucosal myomas (three women), cervical stenosis (one woman), or sustained a uterine perforation during cervical dilation (two women). One patient randomized to REA did not undergo treatment due to a submucosal myoma causing limited cavity access. At baseline, there were no statistically significant differences between the two treatment groups in age, body mass index, PBAC score, uterine cavity length, race, presence of dysmenorrhea or myomas (Table 1). The percentages of women younger than 40 years of age in the MEA and REA groups were 44% and 41%, respectively.

**Treatment Outcomes**

As shown in Figure 4, after 1 year, treatment was successful (i.e., PBAC score 75 or less) in 87.0% of the ITT population treated by MEA. This ITT success rate was similar (p = .40) to that of the REA group (83.2%). There was no evidence of center-to-center heterogeneity in ITT success rate (p = .52). Amenorrhea rates by ITT did not differ significantly between the MEA (55.3%) and REA (45.8%) groups.

Among evaluable patients, success rate at 1 year also was comparable (p = .24) in the MEA (96.4%) and REA groups.

**TABLE 1. Baseline Patient Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>MEA</th>
<th>REA</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>40.5 ± 4.6</td>
<td>40.9 ± 4.6</td>
<td>.48</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>28.0 ± 7.1</td>
<td>27.0 ± 6.6</td>
<td>.25</td>
</tr>
<tr>
<td>PBAC score</td>
<td>451.8 ± 356.6</td>
<td>524.6 ± 429.5</td>
<td>.11</td>
</tr>
<tr>
<td>Uterine cavity length (cm)</td>
<td>8.09 ± 0.98</td>
<td>8.14 ± 0.77</td>
<td>.61</td>
</tr>
<tr>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td>.92</td>
</tr>
<tr>
<td>African-American</td>
<td>22 ± 10.2</td>
<td>12 ± 11.2</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>187 ± 87.0</td>
<td>93 ± 86.9</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>6 ± 2.8</td>
<td>2 ± 1.9</td>
<td></td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td></td>
<td></td>
<td>.76</td>
</tr>
<tr>
<td>Present</td>
<td>176 ± 81.9</td>
<td>86 ± 80.4</td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>39 ± 18.1</td>
<td>21 ± 19.6</td>
<td></td>
</tr>
<tr>
<td>Myomas</td>
<td></td>
<td></td>
<td>.09</td>
</tr>
<tr>
<td>Present</td>
<td>41 ± 19.1</td>
<td>30 ± 28.0</td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>174 ± 80.9</td>
<td>77 ± 72.0</td>
<td></td>
</tr>
</tbody>
</table>

MEA = microwave endometrial ablation; PBAC = pictorial blood loss assessment chart; REA = rollerball electroablation; SD = standard deviation.
(92.7%) groups. The success rate of evaluable patients did not differ significantly among centers (p = .32). Amenorrhea rates were 61.3% and 51.0% for evaluable patients in the MEA and REA groups, respectively, which were not significantly different (p = .102) (Figure 5). An additional 31% of the patients who underwent MEA reported only spotting or hypomenorrhea, for a total of 92% of patients with light or absent bleeding (Figure 5). By 12 months, diary

FIGURE 4. The rate of success (a score of 75 or less on the pictorial blood loss assessment chart [PBAC]) and amenorrhea (0 PBAC score) at 12 months posttreatment in intent-to-treat (ITT) and evaluable treatment groups. Error bars depict CI. Indicated p values are for between-group comparisons. MEA = microwave endometrial ablation; REA = rollerball electroablation.

FIGURE 5. Cumulative percentages of patients achieving pictorial blood loss assessment chart (PBAC) outcome categories at 12 months. MEA = microwave endometrial ablation; REA = rollerball electroablation.
PBAC scores in evaluable patients had decreased from 450 ± 364 (mean ± SD) to 10 ± 34 in the MEA group (p < .0005) and from 501 ± 350 to 24 ± 89 in the REA group (p < .0005).

No effect of patient age (younger than 40 years vs. 40 years or older) or race on success rate could be demonstrated in either the MEA or REA groups. By contrast, among women with body mass index (BMI) of 30 kg/m² or higher, success rates after MEA in the ITT population (85.3%) and among evaluable patients (96.7%) were substantially and significantly greater than the corresponding rates after REA of 66.7% and 81.8%, as shown in Figure 6 (p = .050 and p = .042, respectively).

Success rates at 12 months in patients with myomas vs. those without myomas did not differ significantly between the MEA and REA groups (Figure 7). Among evaluable patients with myomas who underwent MEA, the success rate was 90.3%. These women attained an amenorrhea rate of 61.3% (CI 42.2%–78.2%) compared with 38.5% (CI 20.2%–59.4%) for evaluable women with myomas who underwent REA (Figure 8); however, this difference was not significant (p = .11). In the ITT population, the amenorrhea rate among patients with myomas was also higher after MEA than REA, although the difference was not significant (Figure 8).

At 1 year, 98.5% (193/196) of evaluable women treated with MEA reported that they were satisfied or very satisfied with the treatment compared with 99.0% (96/97) in the REA group. Of women in the MEA group, 89.8% (176/196) entered the study with dysmenorrhea; at 12 months, the frequency of dysmenorrhea was reduced to 33.7% (66/196). Comparable results were recorded in the REA group (89% before and 34% after treatment). SF-36 quality of life scores increased to a comparable extent in both the MEA and REA treatment groups. On the physical component scale, pretreatment scores for the MEA (47.1 ± 9.22) and REA (46.5 ± 8.1) groups increased 54.1 ± 6.6 and 53.6 ± 6.9, respectively, after treatment. On the mental component scale, pretreatment scores for the MEA (46.5 ± 11.5) and REA (46.6 ± 11.4) groups increased posttreatment to 52.2 ± 9.1 and 51.5 ± 9.7, respectively.

Procedure Comparisons

General anesthesia was administered less frequently (p < .001) among women in the MEA (45%) than the REA (78%) group. One clinical site mandated that all participants in the study receive general anesthesia. With exclusion of that site from analysis, general anesthesia was chosen for 37% (67/183) of women undergoing MEA compared with 76% (72/95) of those in the REA group (p < .001); whereas, conversely IV sedation was employed for 62% (113/183) of MEA patients vs. 18% (17/95) of the REA group (p < .001).

Device treatment time (i.e., time during which the energy unit was activated) was significantly shorter in the MEA treatment group. Mean treatment time was 3.45 ± 1.02 minutes for MEA compared with 20.22 ± 15.60 minutes for REA (p < .001).

Adverse Events

There were no device-related complications, and no reports of system or device failure. Procedure-related complications included four cases of cervical laceration (two in
FIGURE 7. The influence of myomas on treatment success rate. MEA = microwave endometrial ablation; REA = rollerball electroablation.

FIGURE 8. The influence of myomas on amenorrhea rate. MEA = microwave endometrial ablation; REA = rollerball electroablation.
each group), one case of cervical stenosis in the MEA group, and two cases of uterine perforation at the time of cervical dilation in the MEA group.

No serious adverse events in the 24 hours after the procedure were reported, as shown in Table 2. Vomiting and uterine cramping occurred significantly more frequently in the MEA treatment group. All cases resolved with conservative management.

In the posttreatment period from 24 hours to 2 weeks, no significant differences in adverse events were observed between the two treatment groups. Uterine cramping was reported in 5.1% of patients in the MEA group and 6.5% of patients in the REA group. Six patients who had undergone MEA treatment developed endometritis, which resolved without complications following antibiotic treatment.

In the posttreatment period of 2 weeks to 1 year, no significant differences in adverse events were noted between the two treatment groups. However, there was a trend toward increased uterine cramping in the MEA group (9%) compared with the REA group (3%).

One patient in the REA group became pregnant and subsequently miscarried. One patient in each group underwent a subsequent hysterectomy, but neither was due to excessive menstrual bleeding. Hysterectomies resulted from pain due to a benign left ovarian mass (MEA group) and patient dissatisfaction with menstrual bleeding 7 months postprocedure despite a PBAC score of 20 (REA group). None of the women underwent repeat endometrial ablation.

Discussion

A successful outcome of a PBAC diary score of 75 or less was achieved in 87% of the ITT group that underwent MEA and 96% of the evaluable patients who underwent MEA. Greater than half of the women treated with MEA—55% in the ITT analysis and 61% in the evaluable group—were amenorrheic at 1 year. In evaluable patients, PBAC diary scores decreased 98%, and 92% of patients had light or absent bleeding at 1 year. Dysmenorrhea decreased from 90% to 34%.

Success rates in both the ITT and evaluable populations were similar in patients undergoing MEA and those undergoing REA. Trends toward higher amenorrhea rates in the MEA group were apparent, although the differences could not be shown to be statistically significant. The total number of patients in both groups with an outcome of amenorrhea was substantially smaller than that with an outcome of treatment success, thus limiting study statistical power to demonstrate a significant difference in amenorrhea rate.

At 1-year posttreatment, approximately 99% of both the MEA and REA groups reported that they were satisfied or very satisfied with treatment results. In an earlier RCT comparing MEA with TCRE, satisfaction/acceptability of the treatment 2 years posttreatment was 79% in the MEA and 67% in the TCRE group. Other studies have also indicated a high satisfaction rate with MEA treatment.

Treatment of myomas remains a challenge with endometrial ablation techniques. As recognized in the protocol of our trial, REA alone is not adequate to treat myomas and must be preceded by loop resection of the myoma. Our results demonstrated that MEA can be used successfully without additional procedures to treat myomas 3 cm or smaller that do not obstruct the uterine cavity. Other studies have also documented successful treatment of myomas by MEA. Another interesting finding of this study was that MEA was significantly more successful than REA in treating women with BMI of 30 kg/m2 or higher.

Rollerball electroablation and TCRE, both of which are operative hysteroscopic techniques, are widely regarded as the gold standard for endometrial ablation. In experienced hands, these procedures have provided attractive alternatives to hysterectomy for menorrhagia due to benign causes. Unfortunately, the high level of technical skill required has hindered the widespread adoption of these approaches. Thermal techniques such as MEA have been designed to be easier to master, require less time to perform, and avoid complications associated with operative hysteroscopy such as fluid overload and hemorrhage.

Microwave endometrial ablation uses high-frequency microwave energy to cause rapid but shallow (5–6 mm) heating of endometrial tissue. Endometrial destruction is achieved through coagulation of the tissue. The relatively low applied power requirement of 30 W further enhances the safety of the device.

The MEA procedure is quickly learned. Investigators in this and other studies have been able to achieve high rates of success with little prior experience of the MEA procedure, and there was no evidence of a greater number of complications in the earlier procedures. Surgeons can usually achieve high proficiency with the technique following three procedures under the guidance of a preceptor. The MEA system console contains a microchip that records the treatment course, which can be reviewed to facilitate the learning process.
Although there is no direct visualization of the uterine cavity during the microwave treatment, real-time monitoring of tissue temperature is accessible on the console display panel. This unique feature that is not shared by second-generation techniques permits the MEA surgeon to tailor the treatment to irregularities and distortions of the uterine cavity such as those caused by fibroids and to deliver the appropriate amount of energy to the fundus, cornu, and corpus areas of the uterus, which differ in thickness. The design of MEA also allows uterine cavities up to 14 cm in length to be treated.

Treatment time for MEA averaged less than 4 minutes compared with more than 20 minutes for the REA procedure. The short treatment time as well as the minimally invasive nature of the procedure are among the factors contributing to choice of IV sedation rather than general anesthesia for the majority of women receiving MEA treatment in the present study. In a randomized comparison of local versus general anesthesia during MEA, local anesthesia was shown to be acceptable in the majority of women.\(^\text{13}\) In addition, a recent MEA study suggested that pretreatment to thin the endometrium may not be necessary. In a randomized comparison of low-dose oral contraceptive, danazol, or no pretreatment, data at 12 months suggested that MEA is equally successful with or without drug pretreatment.\(^\text{15}\)

No serious side effects occurred in either the MEA or REA treatment groups. While vomiting and uterine cramping occurred significantly more frequently in the MEA women in the first 24 hours after treatment, all cases resolved with conservative management.

In a prospective series of 1400 cases of MEA in both teaching and general hospitals in the UK and Canada, only one major complication, a small bowel burn, was encountered.\(^\text{16}\) The authors concluded that MEA appears to be safer than hysteroscopic methods of endometrial ablation. Another case of small bowel injury has also been described.\(^\text{17}\) A total of 27 known cases of injury out of 18,000 procedures have occurred following MEA treatment, corresponding to an incidence rate of 0.15% (CI 0.099%–2%). Of these known cases, 25 cases have involved focal bowel injury, 12 of which were associated with uterine perforation. In the other cases, there was no evident uterine perforation, and a thorough investigation led to the conclusion that the focal bowel injury resulted from an undetected thinned uterine wall due to trauma or prior surgery that permitted microwave energy to pass through an intact uterine wall, inappropriate pretreatment, and/or failure to follow the instructions for use.

Although bowel injury has been a rare adverse event, a number of recommendations are now in place to minimize the risk for this complication. In the clinical trial that is the focus of this report, a transvaginal ultrasound examination to establish a minimum myometrial wall thickness of 8 mm and a diagnostic hysteroscopy after cervical dilation to check for uterine perforation or creation of a false passage were requisite. Transvaginal ultrasound and diagnostic hysteroscopy are now recommended before all MEA procedures, and the required minimum myometrial wall thickness has been increased to 10 mm to augment the margin of safety. The applicator length reading at the start of the procedure should always be in agreement with the prior determination of uterine sounding length. An additional safety feature that is incorporated into the control module—the temperature rise gate—is designed to identify an uncharacteristic temperature rise during the first 5 seconds of treatment that could be indicative of an applicator outside of the uterine cavity. If an uncharacteristic temperature rise is detected, the power to the applicator is terminated. If the temperature reaches 85° C, there is an audible alarm that prompts the physician to move the applicator into an untreated region of the uterus. The device also shuts down if the tissue temperature reaches 90° C, as contrasted with the desired treatment temperature range of 70°–80° C. Preceptorship is now mandated for all new users. Since the new recommendations for use have been instituted, more than 6600 procedures have been performed without any cases of bowel injury.

**Conclusion**

Microwave endometrial ablation is an effective, safe, and versatile treatment for menorrhagia. This approach to endometrial ablation has compared favorably in randomized clinical trials with both REA and TCRE. Furthermore, MEA is easy to master, the procedure can be completed in a fraction of the time required for REA and TCRE, and the majority of women can be treated under IV sedation and local anesthesia. Microwave endometrial ablation resulted in amenorrhea in greater than 50% of the women, and preliminary data indicate that this rate is sustainable 2 years postprocedure.\(^\text{18}\) Women with large, irregular uterine cavities and with submucosal fibroids that do not obstruct the endometrial cavity have also been shown in this study to be suitable candidates for this technique. Microwave endometrial ablation is a nonhysteroscopic thermal endometrial ablation technique that offers distinct advantages for both patients and surgeons.

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References


